

## **Exhibit 8**



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CASE 3528

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of

DAVID C. HECKERT :

Serial No. 860,607 :

Filed May 7, 1986 :

Group Art Unit 132

Examiner C. Paden

FRUIT JUICE BEVERAGES AND

JUICE CONCENTRATES NUTRI-

TIONALLY SUPPLEMENTED WITH CALCIUM

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AMENDMENT PURSUANT TO 37 CFR 1.111

The Commissioner of Patents

and Trademarks

Washington, D.C. 20231

Dear Sir:

In response to the Office Action mailed December 10, 1986, please amend the above application as indicated below. The response period has been extended through May 10, 1987 by petition for a two-month extension of time pursuant to 37 CFR 1.36(a) and payment of the appropriate fee pursuant to 37 CFR 1.17(b).

IN THE SPECIFICATION

At page 16, line 10, change "(4.4°C)" to -- (4.4°C) -- .

At page 20, line 33, change "1" to -- 2.2 -- .

IN THE CLAIMS

In Claim 23, line 2, change "concentrate" to -- concentrated -- .

Please add new Claim 29 as follows:

29. The method of Claim 21 wherein the premix solution of solubilized calcium further comprises a polysaccharide selected from the group consisting of pectin, algins, hydrolyzed starches and xanthan gum in an amount of from about 0.01 to about 0.05% on a weight/volume basis.

REMARKS

Applicant respectfully requests reconsideration of the above application, as amended. After amendment, Claims 1 to 29 are currently pending in the above application.

Applicant would like to thank Examiners Golian and Paden for permitting Applicant, David C. Heckert, Applicant's associate, Timothy W. Dake, and Applicant's attorney, Eric W. Gutttag, to have an interview with them on

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March 2, 1987. This interview is summarized accurately in the Examiner Interview Summary Record. In this Amendment, Applicant's attorney will elaborate further on some of the specific points made during this interview.

Several minor errors in the specification and Claim 23 have been corrected. Also, new Claim 29 has been added which recites that the premix solution comprises certain polysaccharides in specified amounts. Support for this new Claim can be found from a combined reading of lines 1 to 9 and lines 28 to 30 of page 15 of the specification.

During a telephone conversation with Examiner Paden in January, 1987, Applicant's attorney asked whether copending applications Serial No. 813,744 and Serial No. 860,726 (cited in Applicant's Disclosure Statement dated July 28, 1986) were considered for provisional rejections under 35 USC 103 and for obviousness-type double patenting. The Examiner indicated that the copending patent applications had been considered, but did not create provisional rejections with regard to the subject matter claimed in the above application.

Enclosed with this amendment is a Rule 132 Declaration of Timothy W. Dake, one of the participants at the March 2, 1987 interview. This Declaration describes samples which were offered or shown to the Examiners, as well as demonstrations which were conducted during the interview. This Declaration also describes the paneling of calcium-fortified orange juice samples containing various levels of added chloride. The significance of this Declaration will be discussed further in the appropriate sections of this amendment.

I. The Calcium-Supplemented Juice Products of the Present Invention

The present invention relates to products containing at least 45% juice which are nutritionally supplemented with significant levels of calcium. For drinkable, single-strength juice beverages, the level of solubilized calcium can be from about 0.05 to about 0.26% by weight. See Claims 1-11. Preferred juice beverages contain from about 0.10 to about 0.15% by weight, e.g. milk level. See Claim 8. In addition to drinkable juice beverages, the present invention also relates to calcium-supplemented juice concentrates which can be used to prepare such beverages. See Claims 12 to 18, and in particular Claim 16.

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II. The Premix Method of the Present Invention Provides These Calcium-Supplemented Juice Products, but Without the Problems Caused by Direct Addition of Calcium Sources to Juice or Juice Concentrate.

The calcium-supplemented juice products of the present invention are preferably obtained by using what is referred to as the "premix method." See Claims 19 to 29. In this premix method, an at least meta-stable solution of solubilized calcium is formed from: (1) water; (2) malic acid, or preferably a mixture of malic and citric acid; and (3) calcium hydroxide, calcium oxide, or calcium carbonate. This meta-stable solution of solubilized calcium is combined with concentrated juice, plus other juice materials such as aroma and flavor volatiles, pulp and peel oils, to provide the calcium-supplemented juice products. The Figure for the above application illustrates a preferred embodiment of the premix method where the premix solution is prepared by adding acids to water to form an acid solution to which is then added calcium carbonate or calcium hydroxide (see Claim 20). It is also preferred to use stabilizers such as sugars, concentrated juice or polysaccharides such as pectin to keep the calcium solubilized in the premix solution for extended periods (see Claims 23, 24 and 29).

At the March 2, 1987 interview, calcium-supplemented orange and grapefruit products containing 60% juice made by this premix method were offered to the Examiners. The products shown in photograph 1 attached to the Rule 132 Declaration of Timothy W. Dake are representative of what were offered. As described in paragraph 4 of this Declaration, these products were prepared from the respective calcium-supplemented orange or grapefruit juice concentrates of the present invention. See also paragraph 5 of this Declaration which describes how these orange and grapefruit juice concentrates were prepared according to the premix method of the present invention.

In providing these calcium-supplemented juice products, the premix method of the present invention avoids the potential problems which can be caused by direct addition of calcium sources to juice or juice concentrates. This was amply shown at the interview by demonstrations involving the direct addition of calcium hydroxide or calcium carbonate to orange juice or orange juice concentrate. The demonstrations which took place at this interview are described in paragraphs 6 to 8 of Mr. Dake's Rule 132 Declaration, the results of which are shown in attached photographs 2 and 4.

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Two demonstrations involving the direct addition of calcium hydroxide to orange juice were conducted. These demonstrations are believed to be representative of what occurs during the direct addition of calcium hydroxide to orange juice or orange juice concentrate in a large blend tank typically used in commercial citrus juice operations. These large blend tanks mix the ingredients in such a way that fairly high, localized concentrations of calcium hydroxide can result in the juice or juice concentrate.

In the first demonstration, sufficient calcium hydroxide was added to the orange juice to provide a calcium content, if completely dissolved, of 0.24%. It was very difficult to dissolve the calcium hydroxide in the juice, even with vigorous hand stirring. As shown in photograph 2, the color of the orange juice significantly darkened after calcium hydroxide addition. Indeed, the color of the juice actually became green in color at the interview.

In the second demonstration, sufficient calcium hydroxide was added to the orange juice to provide a calcium content, if completely dissolved, of 0.48%. Like the first demonstration, it was very difficult to dissolve the calcium hydroxide in the juice. As shown in photograph 3, the color of the juice again darkened after calcium hydroxide addition. Also, a gel formed which separated out. It is believed that this gel is the result of pectin in the juice which has been demethoxylated by the hydroxide and then reacted with the calcium. Also, the juice quickly developed a fishy, amine odor. It is believed that this odor is due to the breakdown of proteins and amino acids present in the juice.

The demonstration involving direct addition of calcium carbonate to orange juice concentrate is representative of what would occur in a blend tank typically used in commercial citrus juice operations. In this demonstration, a mixture of calcium carbonate, citric acid and malic acid was added to orange juice concentrate. (If completely dissolved, this would provide a calcium content, total acid level and weight ratio of citric to malic acid within that defined in Claim 12 of the above application.) It was difficult to completely dissolve this mixture of calcium carbonate, citric acid and malic acid in the orange juice concentrate, even with vigorous hand stirring. As shown in photograph 4, the orange juice concentrate foamed considerably after addition of this mixture due to carbon dioxide evolution as the result of the reaction of calcium carbonate with the acids. This foaming would make pumping and further processing of the concentrate difficult.

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To summarize, calcium supplementation of juice products is not as easy as adding calcium to juice. The calcium must be solubilized in the juice. Also, potential problems such as deterioration of juice quality (e.g., color generation and gel formation), the addition or generation of unpleasant-tasting or smelling materials (e.g., odor), the removal of desirable juice volatiles, as well as other processing problems (e.g., foaming), must be avoided. Direct addition of calcium sources does not solve these problems. The premix method of the present invention does.

III. Claims 19 to 27 and 29, which relate to the preparation of calcium-supplemented juice products by forming a premix solution of solubilized calcium and then combining the premix solution with concentrated juice and other juice materials, are unobvious under 35 USC 103 over Nakel et al, even in view of Sperti et al.

The Examiner has rejected Claims 19 to 27 under 35 USC 103 as unpatentable over U.S. Patent 4,551,342 (Nakel et al), in view of U.S. Patent 3,114,641 (Sperti et al). Basically, the Examiner relies on Nakel et al to disclose the preparation of a "premix" from an aqueous solution of citric, malic and phosphoric acid to which calcium carbonate and magnesium carbonate have been added. This "premix" is then combined with a beverage syrup. The Examiner then relies on Sperti et al, which teaches extended citrus juice products containing calcium chloride, citrates and malic acid, to argue that it would be obvious to substitute orange juice for the beverage syrup of Nakel et al "since both Nakel et al and Sperti et al are directed to flavored beverages generally."

Applicant must respectfully disagree. Unlike the claimed premix method of the present invention, presolubilization of calcium and acids before addition to juice is not critical to either Nakel et al or Sperti et al. Nakel et al is primarily directed at carbonated soft drinks which may or may not contain juice. Sperti et al says that their salts and acids can be added to either: (a) the juice or concentrate; (b) the water used to extend their juice products; or (c) the extended juice product itself. Indeed, Sperti et al even suggests addition to the juice or concentrate is preferred (see Column 5, line 70, to Column 6, line 5).

The Examiner recognizes that the juice products obtained by the claimed premix method have a higher calcium content, but argues that this variation is obvious. Applicant must respectfully disagree. Unlike the claimed premix method, Nakel et al and Sperti et al are not directed at supplementing juices



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with high levels of solubilized calcium. Instead, Nakel et al uses a mixture of cations (calcium, potassium and preferably magnesium) to improve mouthfeel (body) of beverages without imparting the off-notes of any particular cation. Indeed, Nakel et al say this mixture of cations is critical to the mouthfeel and taste properties of their beverages. Sperti et al uses a variety of additives in "very small amounts" to improve the flavor of their extended juice products. Indeed, Sperti et al doesn't require calcium as an additive (see formula at Column 5, lines 40 to 62).

As was emphasized at the interview, the claimed premix method of the present invention provides calcium-supplemented juice products having significant levels of calcium, i.e. at least about 0.05% solubilized calcium. By contrast, Nakel et al and Sperti et al only teach low level addition of calcium to beverage products. For Embodiments 1 to 9 of Nakel et al, calcium levels range from 0.014 to 0.045% for carbonated beverages which do not contain juice. In the case of Sperti et al, the highest calcium level disclosed is only 0.014% (see Column 5, line 15).

Moreover, scale-up of the Nakel et al, and especially the Sperti et al technology, to achieve the preferred higher calcium levels (0.10 to 0.15%) desired by the present invention would yield beverages having excessive saltiness. As described in paragraph 9 of Mr. Dake's Rule 132 Declaration, a sample of single-strength orange juice to which calcium chloride had been added was offered to the Examiners. (Calcium chloride is the calcium salt used in the Sperti et al extended juice products.) The amount of calcium chloride added would provide, in the juice, a calcium level of 0.13% and a chloride level of 0.21%. The salty note imparted by this level of chloride was clearly picked up by the Examiners at the interview.

The Examiner also says the use of concentrated orange juice (Claim 23) or sugar (Claim 24) in the premix solution of the claimed method "is seen to be a matter of choice." Applicant must respectfully disagree. As taught at page 15 of the specification, lines 1 to 15, orange juice concentrate and sugar act as crystallization inhibitors to stabilize the calcium malate and especially citrate species in the premix solution. See also new Claim 29 where certain polysaccharides are also used as premix stabilizers. As previously noted, Nakel et al and Sperti et al are not concerned with the presolubilization of calcium prior to addition to juice. Accordingly, these references would not suggest the use of premix stabilizers according to the premix method defined in Claims 23, 24 and 29.

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IV. Claim 28, which defines a calcium-supplemented fruit juice product made by the premix method of the present invention, is novel under 35 USC 102(b) and unobvious under 35 USC 103 over Kaji et al or Aktins et al.

The Examiner has rejected Claim 28 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103 as obvious over Japanese Patent Document 54-8767 (Kaji et al) or U.S. Patent 3,657,424 (Aktins et al). The Examiner says these references are directed to fortified juice products. She further argues that the fact that the product may have been made by a different method doesn't make it unobviousness, citing In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

Applicant agrees, as was held in the Thorpe case, that the patentability of "product-by-process" claims must be based on the product itself. However, Applicant disagrees with the Examiner's position that Kaji et al or Aktins et al disclose, or even suggest, the calcium-supplemented juice products of Claim 28. Kaji et al doesn't teach calcium fortification of beverages containing significant amounts of juice, i.e. at least 45% juice as defined in Claim 28. Instead, the calcium-enriched soft drinks of Kaji et al contain minimal juice (about 4% by weight based on the one example given). Moreover, there is no suggestion that the Kaji technology would be applicable to beverages containing much higher levels of juice.

Aktins et al doesn't teach fortification of citrus juice with high levels of calcium, i.e. about 0.05% or higher as defined in Claim 28. The fortified citrus juices of Aktins et al contain only low levels of added calcium (a maximum of 0.014% based on addition of the preferred calcium chloride salt). Indeed, the maximum permissible amount of calcium salt that Aktins et al says can be added is 0.04% (see Column 2, line 70, to Column 3, line 1). This would, in fact, teach away from fortification of citrus juices with higher levels of calcium, as in the calcium-supplemented juice products of Claim 28.

V. Claims 1 to 18, which define calcium-supplemented juice beverages and juice concentrates which contain high levels of solubilized calcium without the salty note imparted by too high a level of chloride ion, are unobvious under 35 USC 103 over Sperti et al, even in view of Kaji et al.

The Examiner has rejected Claims 1 to 18 under 35 USC 103 as unpatentable over Sperti et al, apparently in view of Kaji et al. The Examiner relies on Sperti et al to teach citrus drinks which are formulated with added calcium chloride, sucrose and citrate and to show that malic acid is a buffer commonly used in orange juice. She further relies on Kaji et al to



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teach calcium-fortified carbonated fruit drinks containing 0.6% calcium and a 1 to 1 weight ratio of citrate to malate. Accordingly, she argues it would be obvious to utilize the calcium level and citric to malic ratio of Kaji et al in the fruit drink of Sperti et al.

Applicant respectfully submits that the calcium-supplemented juice beverages and juice concentrates of Claims 1 to 18 are unobvious over each of these references alone, or in combination. The calcium chloride addition taught by Sperti et al is satisfactory only for low levels of calcium. Based on adding 0.04% calcium chloride as taught in the example at Column 5, lines 9 to 20, the Sperti extended juice products contain only 0.014% calcium. By comparison, the juice beverages of Claims 1 to 12 contain at least about 0.05% solubilized calcium, while the juice concentrates of Claims 13 to 18 contain at least about 0.15% solubilized calcium.

Moreover, adding more calcium chloride to achieve higher calcium levels will cause excessive saltiness due to the resulting higher levels of chloride. This is especially true if sufficient calcium chloride were added to achieve the preferred calcium level of 0.10 to 0.15% defined in Claim 8. If calcium chloride were used as the only calcium source, the level of chloride would be from 0.18 to 0.27%, far higher than the maximum of about 0.07% chloride defined in Claim 1. As was shown at the interview, juice products fortified solely with calcium chloride to achieve milk level calcium (about 0.12%) had a definite salty note imparted by the chloride.

Indeed, juice products fortified to milk level calcium, but only partially with calcium chloride as the source of calcium, impart a recognizable salty note at chloride concentrations above the maximum defined in Claim 1. As described in paragraph 12 of Mr. Dake's Rule 132 Declaration, samples of orange juice containing milk levels of calcium to which have been added 0, 0.043%, 0.086%, and 0.129% chloride (from calcium chloride dihydrate) were paneled. The sample containing 0.043% chloride (below the maximum level defined in Claim 1) was not considered statistically different in terms of salty/brackish taste from the sample containing no added chloride. By contrast, the samples containing 0.086% and 0.129% added chloride (above the maximum level defined in Claim 1) were considered to be statistically more salty/brackish in taste compared to the sample containing no added chloride.

In addition, Sperti suggests using mostly citric acid, and very little malic acid, in their extended juice products. Based on the example given in Column 5, lines 19-20, the Sperti et al extended juice products contain at

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least 99% citric acid/citrate combined, and less than 1% malic acid. The Examiner should note that the weight ratio of citric acid:malic acid defined in Claim 1 is no greater than 90:10. At the weight ratio of citric acid:malic acid suggested by Sperti et al, calcium might precipitate out of the juice at very high levels, e.g., at calcium levels of 0.10 to 0.15% defined in Claim 8.

Kaji et al teaches calcium fortification at too high a level for single-strength beverages. The Kaji et al enriched soft drinks contain, on a calculated basis, 0.6% calcium. By contrast, the maximum calcium level specified for the juice beverages of the present invention in Claim 1 is about 0.26%. Calcium, at the level disclosed by Kaji et al, can precipitate out of single-strength beverages.

The precipitation potential of the Kaji et al enriched drinks is graphically demonstrated by photograph 5 attached to Mr. Dake's Rule 132 Declaration. The Kaji et al samples in the photograph, with and without vinegar, were shown to the Examiners at the interview. As can be seen, even the sample with vinegar, which is made by the preferred method disclosed in Kaji et al, has a brown precipitated solid at the bottom, which is believed to contain calcium citrate. The level of vinegar in this sample is so high as to make it virtually unpalatable. However, as shown by the sample without vinegar, even more material will precipitate out (as calcium citrate) if vinegar is not added.

Applicant also challenges the Examiner's basis for combining the teachings Kaji et al with those of Sperti et al. As previously noted, in part IV of this amendment, Kaji et al doesn't teach calcium fortification of products containing significant levels of juice, i.e., at least 45% juice as defined in Claims 1 to 18. Nor is there any suggestion that the Kaji et al technology would be applicable to beverages containing much higher levels of juice. Accordingly, Applicant questions how the Examiner can even apply the teachings of Kaji et al to the Sperti et al extended juice products.

#### VI. Conclusion

Applicant respectfully submits that the premix method of Claims 19 to 27 and 29 is unobvious over the prior art relied on. Unlike the claimed premix method of the present invention, presolubilization of calcium and acids before addition to juice is not critical to either Nakel et al or Sperti et al. These references are also not directed at supplementing juices with high level of solubilized calcium. Instead, these references only disclose low level addition of calcium to beverage products. Moreover, scale-up of the Nakel et al, and

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especially the Sperti et al technology, to achieve the preferred higher calcium levels (0.10 to 0.15%) desired by the present invention would yield beverages having excessive saltiness.

Applicant also submits that the calcium-supplemented fruit juice product made by the premix method of the present invention, as defined in Claim 28, is novel and unobvious over the prior art relied on. Kaji et al doesn't teach calcium fortification of beverages containing significant amounts of juice as defined in Claim 28. Aktins et al doesn't teach fortification of citrus juice with high levels of calcium as defined in Claim 28.

Applicant further submits that the calcium-supplemented juice beverages and juice concentrates of Claims 1 to 18 are unobvious over the prior art relied on. Calcium chloride addition taught by Sperti et al is satisfactory only for low levels of calcium. Moreover, adding more calcium chloride to achieve higher calcium levels will cause excessive saltiness due to the resulting higher levels of chloride. Kaji et al teaches calcium fortification at too high a level for single-strength beverages. Moreover, since Kaji et al doesn't teach calcium fortification of products containing significant levels of juice, Applicant challenges the Examiner's basis for combining the teachings of this reference with those of Sperti et al.

For these reasons, Applicant respectfully requests that a patent be allowed to issue on Claims 1 to 29 currently pending in the above application.

Respectfully submitted,

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